

WHAT IS CLAIMED IS:

1. A method for continuous determination of a target analyte in a sample comprising the steps of:

5 (a) contacting an analyte with an immunosensory apparatus comprising a working electrode having a binder on its surface and a reference electrode and wherein said working electrode requires no regeneration between consecutive measurements of the analyte;

(b) determining a change in the working electrode potential, and

10 (c) comparing the potentiometric response of the working electrode with the reference electrode wherein a difference indicates the presence of analyte in said sample and said difference is proportional to the concentration of analyte, and wherein said measurement can be performed with a single working electrode, thereby determining the concentration of said analyte in the sample.

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2. The method of claim 1 wherein said analyte is selected from the group consisting of an antigen, a hapten and an antibody.

20 3. The method of claim 1 wherein said labeled detection compound is selected from the group consisting of an antigen, a hapten and an antibody.

4. The method of claim 1 wherein said labeled detection compound is the same as the analyte.

25 5. The method of claim 1 wherein said labeled detection compound is a binder for the analyte.

6. The method of claim 1 wherein the binder is a binder for both the analyte and the labeled detection compound.

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7. The method of claim 1 wherein the analyte binds reversibly to the binder.

8. The method of claim 1 wherein said electrocatalytic enzyme an oxidoreductase.

5           9. The method of claim 1 wherein said electrocatalytic enzyme is a member selected from the group consisting of laccase, lactate dehydrogenase, horseradish peroxidase, cytochrome c peroxidase, a fungal peroxidase, lactoperoxidase, microperoxidase, chloroperoxidase, hydrogenase, D-fructose dehydrogenase, methylamine dehydrogenase, flavocytochrome c552, succinate dehydrogenase, 10 fumarate reductase, alcohol dehydrogenase, D-gluconate dehydrogenase, cellobiose dehydrogenase and ascorbate oxidase.

10. The method of claim 1 wherein said electrocatalytic enzyme is laccase.

15           11. The method of claim 1 wherein the diffusion medium is a liquid or a gel.

12. The method of claim 1 wherein said diffusion medium contains a second substrate for the electrocatalytic enzyme and the analyte binds to one of either the binder on said working electrode or the detection compound.

20           13. The method of claim 12, wherein said second substrate is oxygen.

14. A method for determining a target analyte in a sample comprising the steps of:

25           (a) contacting an analyte with an immunosensory apparatus, comprising a diffusion membrane, a reference electrode and a working electrode, the latter having on its surface a binder with a labeled detection compound attached thereto, wherein said electrodes and said membrane are separated by a chamber containing a diffusion medium that contains a substrate of an electrocatalytic 30 enzyme and wherein said electrodes are separated from the source of said analyte

by said membrane, under conditions promoting diffusion of said analyte through said membrane to contact said electrodes;

(b) allowing the analyte to displace the labeled detection compound from said binder whereupon said analyte becomes bound to the binder on the surface of the working electrode in the case where the detection compound is the same as the analyte or the analyte becomes bound to the detection compound in the case where the labeled detection compound is a binder for the analyte, and wherein said detection compound is bound to an electrocatalytic enzyme such that in the presence of the target analyte the working electrode provides an electron to said electrocatalytic enzyme which provides an electron to a substrate of said enzyme

(c) determining a change in the working electrode potential, and

(d) comparing the potentiometric response of the working electrode with the reference electrode wherein a difference indicates the presence of analyte in said sample and is proportional to the concentration of analyte,

thereby determining the concentration of analyte in the sample.

15. The method of claim 14 wherein electrode regeneration is not required between successive determinations of said analyte.

16. The method of claim 14 wherein regeneration of the working electrode and other reagents is not required between successive determinations of said analyte.

17. A method for intermittently or continuously conducting immunoassay measurements wherein a plurality of different measurements for an analyte are available for a single electrode without requiring regeneration of said electrode and other reagents, wherein said method is for determining a target analyte based on displacement activity of the target analyte and a potentiometric mode, said method comprising the following steps:

(a) immersing of the intermediate and/or continuous bioelectrocatalysis immunoassay sensing element of claim 8 in a assay medium containing the target analyte,

5 (b) allowing the target analyte of the assay medium to diffuse through the diffusion membrane of the sensing device and travel to the surface of the working electrode,

10 (c) permitting an immuno-equilibrium to be established within the sensing device with respect to the amount of target analyte present in the assay medium due to displacement of some or all of a labelled detection compound from the binder on the surface of the electrode by the target analyte which target analyte becomes bound to the binder on the surface of the sensing element in the case where the detection compound is the same as the analyte or the target analyte becomes bound to the detection compound in the case where the detection compound is a binder for the analyte,

15 (d) measuring at least one shift of the electrode potential caused by the displacement of some or all of the labeled detection compound from the electrode's surface and the resulting diminishment or absence of electrocatalytic properties caused by the label of detection compound,

20 (e) determining the potentiometric sensor response which is proportional to the degree of displacement of the labeled detection compound from the binder on the surface of the working electrode caused by competitive binding of the target analyte, and

25 (f) determining the concentration of the target analyte in the external media from the potentiometric sensor response as compared with the control electrochemical reference electrode.